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Response to 12/16/2005 Office Action

Remarks/Arguments

In the 12/06/2004 Office Action, it was provided that the request for continued examination filed 37 CFR 1.114 was entered.

In said Office Action, claims 22-23, 25, 27-28, and 30 were rejected under 35 USC 103(a) as being unpatentable over Elliott, et al., WO 00/50380 in view of The Merck Manual of Diagnosis and Therapy (1999) in combination with Busch et al., WO 97/42190 or Uban, US Patent No. 5,359,068 in view of Preskorn, Outpatient Management of Depression (1999). Applicant respectfully traverses. The cited references do not make Applicant's invention obvious for the following reasons.

The 12/16/2004 Office action states on page 3:

Elliott reference does not teach the combination of atypical antipsychotic agent ziprasidone with the SRI antidepressant [2-(3,4-dichlorophenoxy)-5-fluorobenzyl]-methylamine.

The 12/16/2005 Office Action states at page 4:

Preskorn in the analogous art, teaches a combination treatment using antidepressants and antipsychotics (see the reference).

One of ordinary skill in the art would have been motivated to combine the reference teachings by selecting the two compounds independently taught in the references in a single therapeutic administration because the skilled artisan would have expected the combination to have the same properties and activities taught for the individual compounds as both compounds are taught to exhibit similar properties. [T]he idea of combining the references flows logically from their having been individually taught in the prior art. *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

.... "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose." See MPEP § 2146.06. Furthermore, Preskorn teaches the combined treatment using antidepressants plus antipsychotics. [Emphasis in original.]

The present invention concerns:

A method of treating depression, obsessive disorder, and psychosis in a mammal, comprising administering to said mammal: (a) a compound that exhibits activity as an SRI antidepressant, or a pharmaceutically acceptable salt thereof; and (b) an atypical antipsychotic or pharmaceutically acceptable salt thereof; wherein the active agents "a" and "b" above are present

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in amounts that render the combination of the two agents effective in treating, respectively, depression, obsessive compulsive disorder, and psychosis, wherein the atypical antipsychotic agent, or pharmaceutically acceptable salt thereof, is administered in an amount from about 0.05 mg per day to about 1500 mg per day, and the antidepressant, or pharmaceutically acceptable salt thereof, is administered in an amount from about 0.05 mg day to about 1500 mg per day.

Preskorn discusses treatment options to address adverse effects from medication used to treat a person for depression. Preskorn also discusses augmentation strategies. It is noted that such a strategy is a planned drug-drug interaction. The article states: "The most frequent augmentation strategies involve the addition of lithium, thyroid hormone, or psychostimulants to antidepressants. More recently, agents such as pindolol and buspirone have also been tried." Preskorn, p. 7 of the printout with the 12/16/2004 OA. Preskorn further states, with regard to combining an antidepressant plus antipsychotics: "There are also patients who have both depressive and psychotic symptoms (eg, mood congruent hallucinations or delusions). . . . When treated with an antidepressant alone, these patients often do not improve. A better strategy for such patients is combined treatment with an antidepressant and **an antipsychotic or alternatively electroconvulsive therapy.**" Preskorn, *supra*, at 9-10, emphasis added.

Many types of combinations are found in Preskorn; however, what is not found within said article is the combination of Applicant's invention: a SRI compound with an atypical antipsychotic. The discussion by Preskorn concerns many types of agents, but atypical antipsychotics are not among them. For a discussion on atypical antipsychotics, see Elliott Richelson, M.D., *J. Clin. Psychiatry*, (v 60) 1999 (suppl 10), pp 5-14. A lack of continuity for the proposition in the 12/16/2004 Office Action is the failure to show that the sought after drug-drug interactions of Preskorn would be applicable with Applicant's invention due to the differences in compounds between the reference and pending application. Applicant respectfully disagrees that Preskorn is analogous art teaching the combination of Applicant's invention due to the differences in the compounds and therapy between Preskorn (electroconvulsive therapy is also suggested) and Applicant's invention (SRI and atypical antipsychotic).

Moreover, the rejection pending is a section 103 obviousness rejection. There are certain burdens to overcome by the PTO with such rejections:

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Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching suggestion or incentive supporting the combination. *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). [*In re Geiger*, 815 F.2d 686, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987).]

As already provided, it is uncontested that Elliott does not teach the combination of atypical antipsychotic agent ziprasidone with the SRI antidepressant [2-(3,4-dichlorophenoxy)-5-fluorobenzyl]-methylamine. Applicant asserts that Busch and Urban also do not teach said combination. Furthermore, Preskorn concerns antipsychotics that are not atypical and includes other types of therapy, such as electroconvulsive therapy, and, therefore, should be found to be inappropriate for a reference for the pending invention.

The references have been improperly combined using hindsight of Applicant's invention to piece together information to claim that Applicant's invention is obvious. It is improper to rely on the conclusory statement that one of ordinary skill in the art would so combine the teachings of the separate references without some objective support for such a combination.

Applicant respectfully requests that the 103 rejection be withdrawn and the claims allowed.

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Conclusion

Applicants believe that the claims are in order for allowance, early notice of which is requested. If Examiner has any questions concerning this application, Examiner is invited to contact the below-signed attorney.

Respectfully submitted,

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Date: 15 June 2005

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